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Joan H. Krause

Richard S. Saver

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HEALTH CARE DECISIONS IN THE NEW ERA OF HEALTH CARE REFORM: AN OVERVIEW*

JOAN H. KRAUSE** & RICHARD S. SAVER***

“Some problems are so complex that you have to be highly intelligent and well informed just to be undecided about them.”
– Laurence J. Peter, *Peter’s Almanac*.¹

Peter’s wry observation, while not specifically about health care, aptly captures this symposium’s key themes. This symposium considers decision-making challenges in health care. The subject is timely, with the push to improve decision making as part of health care reform, and yet also timeless.

Centuries ago, the famous medieval physician and philosopher Maimonides observed that “the risk of a wrong decision is preferable to the terror of indecision.”² Several decades ago, renowned sociologist Renée Fox conducted seminal studies documenting how physicians struggle with uncertainty throughout their professional training and medical practice.³ Fox identified three broad categories of uncertainty that complicate health care: the difficulty in mastering vast sums of medical knowledge; the limitations of current medical

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** Dan K. Moore Distinguished Professor of Law and Associate Dean for Faculty Development, University of North Carolina School of Law; Professor (Secondary Appointment), University of North Carolina School of Medicine; Adjunct Professor, University of North Carolina Gillings School of Global Public Health.

*** Arch T. Allen Distinguished Professor of Law, University of North Carolina School of Law; Professor (Secondary Appointment), University of North Carolina School of Medicine; Adjunct Professor, University of North Carolina Gillings School of Global Public Health.

1. LAURENCE J. PETER, *PETER’S ALMANAC* (1982), *quoted in* LIBRARY OF CONGRESS, *RESPECTFULLY QUOTED: A DICTIONARY OF QUOTATIONS REQUESTED FROM THE CONGRESSIONAL RESEARCH SERVICE* 78 (Suzy Platt ed., 1989).

2. *Quoted in* David Gurwitz & Jeantine E. Lunshof, *Personalized Participatory Medicine: Sharing Knowledge and Uncertainty*, 3 *GENOME MED.* 69, 69 (2011), *available at* <http://genomemedicine.com/content/pdf/gm285.pdf>.

3. *See* RENÉE C. FOX, *EXPERIMENT PERILOUS: PHYSICIANS AND PATIENTS FACING THE UNKNOWN* 28–39 (1959); Renée C. Fox, *Training For Uncertainty*, in *THE STUDENT PHYSICIAN: INTRODUCTORY STUDIES IN THE SOCIOLOGY OF MEDICAL EDUCATION* 207, 207–41 (Robert K. Merton et al. eds., 1957).

knowledge itself; and problems physicians face in distinguishing between their own personal ignorance and the imperfect current state of medical science.⁴ Fox noted the paradox that "our great . . . progress in medical science and technology has helped to reveal how ignorant, bewildered, and mistaken we still are in many ways about health and illness, life and death."⁵

Decades after Fox's groundbreaking work, physician David Eddy, in a widely cited article published in 1984, connected the critical role of uncertainty to significant health policy concerns, such as the wide variation in the way physicians practice medicine.⁶ Eddy observed that a myriad of factors make health care decisions so difficult and seemingly discordant:

Uncertainty creeps into medical practice through every pore. Whether a physician is defining a disease, making a diagnosis, selecting a procedure, observing outcomes, assessing probabilities, assigning preferences, or putting it all together, he is walking on very slippery terrain. It is difficult for nonphysicians, and for many physicians, to appreciate how complex these tasks are, how poorly we understand them, and how easy it is for honest people to come to different conclusions.⁷

The point is that decision making in health care, while ever-challenging and of serious concern today for health policy, has always been difficult and often suboptimal. Despite their aura of competent precision rooted in scientific training, physicians regularly grapple with incertitude, doubt, and chance. Indeed, medicine, at its core, is a profession rife with uncertainty.⁸ Among other reasons, the multiple treatment pathways that are possible for a particular condition, combined with how patients respond differently to the same intervention, and the difficulty in measuring and valuing outcomes, routinely present decision-making challenges for physicians in clinical practice.

The decision-making difficulties are not limited, however, to health care providers. On the other side of the treatment relationship, patients regularly struggle with charting the course of their medical

4. Fox, *Training For Uncertainty*, *supra* note 3, at 208-09.

5. Renée C. Fox, *The Evolution of Medical Uncertainty*, 58 MILBANK MEMORIAL FUND Q. HEALTH & SOC'Y 1, 1 (1980).

6. See David M. Eddy, *Variations in Physician Practice: The Role of Uncertainty*, HEALTH AFF., May 1984, at 74, 75.

7. *Id.*

8. See JEROME GROOPMAN, HOW DOCTORS THINK 151-52 (2008).

care. Countless narratives by patients and their family members describe the crippling and frustrating process of making health care decisions. One recent noteworthy addition is Pulitzer Prize winning reporter Amanda Bennett's 2012 book, *The Cost of Hope*.⁹ In this memoir, Bennett details her husband's fight with and eventual death from kidney cancer. She poignantly describes how the "hundreds of decisions we made over seven years . . . illustrate the impossible calculus at the core of life, of love of family, and of the U.S. health care debate."¹⁰ The bills for her husband's care totaled \$618,616, almost two-thirds of which was spent for care during his final two years, and much of which was spent on treatments that she still is not sure extended his life.¹¹ Bennett laments the health care system's opacity and the troubling uncertainty that remains despite all the hardships endured by her family:

And what can we do about a system that is so maddeningly complex to navigate? One that took days, weeks, months, even whole years of our lives to figure out? One that leaves me, even today, four years after Terence's death, not entirely sure we did the right thing? Why was this system designed for the doctors, hospitals, laboratories, and technicians and not for Terence and me?¹²

As Bennett's memoir illustrates, patients following the many paths and pitfalls of the health care system must make countless difficult decisions that implicate wide-ranging considerations, including of science, emotion, and cost.

Moving one level up from doctors and patients, other key stakeholders in the health care system consistently confront decision-making problems as well. Health care payers (insurers, employers, etc.) have considerable difficulty deciding which interventions to cover and which to exclude as the marginal benefit of certain treatments often remains unclear. For example, consider the recent outcry over the Medicare program's decision to limit reimbursement for amyloid brain scans for diagnosing Alzheimer's disease, despite pleas from patient groups that the scans have important value because the underlying disease has few proven therapeutic interventions.¹³ Large networks of providers, such as accountable care

9. AMANDA BENNETT, *THE COST OF HOPE* (2012).

10. *Id.* at 5.

11. *Id.*

12. *Id.* at 223.

13. See *Decision Memo for Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (CAG-00431N)*, CENTERS FOR MEDICARE &

organizations (“ACOs”), also run into decision-making quandaries. In trying to coordinate care and control costs within their provider networks, ACOs must decide how best to implement standardized policies affecting large groups of patients with different needs. Likewise, ACOs must choose between policies that negatively impact certain network providers (such as reduced income) more than others.¹⁴ Decision-making challenges also reach the level of health care regulators. Health care agencies’ regulatory choices have become all the more complex and confounding due to rapid information flow concerning medical treatments and an ever-expanding number of measures deployed to assess health outcomes and quality.¹⁵

Why does decision making remain so difficult when it comes to health care? To start, the quantity and complexity of clinical information presents cognition challenges not only for patients¹⁶ but also for providers.¹⁷ But the decision-making difficulties go deeper than just the fact that clinical information can be quite complicated. Decision-making problems pervade health care for many additional reasons, many of which our symposium authors explore further. These include: (1) treatment decisions can be emotionally charged, involving high-stakes consequences of life and death; (2) the lack of a solid evidence base as to how many commonly offered treatments compare to each other;¹⁸ (3) important treatment decisions may not be answerable by clinical expertise alone, but instead depend critically on the individual patient’s personal values and preferences,¹⁹

MEDICAID SERVICES (Sept. 27, 2013), [http://www.cms.gov/medicare-coverage-database/shared/handlers/highwire.ashx?url=http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx@@@NCAId\\$\\$\\$265&session=whzd4i552jssnmixrroz3mx&kq=1506488529](http://www.cms.gov/medicare-coverage-database/shared/handlers/highwire.ashx?url=http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx@@@NCAId$$$265&session=whzd4i552jssnmixrroz3mx&kq=1506488529); Judith Graham, *Decision Casts Doubt on Brain Scans for Alzheimer’s*, NEW OLD AGE BLOG (Aug. 1, 2013, 5:00 AM), <http://newoldage.blogs.nytimes.com/2013/08/01/doubt-on-brain-scans-for-alzheimers/>.

14. See Timothy G. Ferris, *Building an Accountable Care Organization*, HARV. BUS. REV. BLOG NETWORK (Sept. 25, 2013, 1:00 PM), <http://blogs.hbr.org/2013/09/building-an-accountable-care-organization/>.

15. See Kristin Madison, *Regulating Health Care Quality in an Information Age*, 40 U.C. DAVIS L. REV. 1577, 1579–81 (2007).

16. See, e.g., JULIA JAMES, HEALTH AFFAIRS, *Patient Engagement* 1 (2013), available at http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_86.pdf.

17. See, e.g., Madison, *supra* note 15, at 158–83.

18. See Richard S. Saver, *Health Care Reform’s Wild Card: The Uncertain Effectiveness of Comparative Effectiveness Research*, 159 U. PA. L. REV. 2147, 2170–75 (2011).

19. See Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 448 (2006) (“[E]ven if physicians agreed on a standard of care, for some conditions there is no single standard treatment appropriate for all individuals, indicating that patient values and preferences are integral to choosing the best treatment option.”).

which can be highly variable and context dependent; (4) severe information gaps as to cost and quality that hamper not only patients, but payers, providers, and regulators of health care; (5) the health care market largely depends on third-party payment, which introduces agency costs, moral hazard, and additional complexities that can lead to suboptimal consumption decisions concerning health care services;²⁰ (6) the true value of many health care treatments is not easily answerable or quantifiable, especially for treatments that offer some modest improvement in therapeutic outcome but at high marginal cost;²¹ (7) it remains difficult to spell out, as a matter of law via standard contract or statutory terms, what services are necessary and should be covered by health care financing and what can be excluded as unnecessary;²² and (8) despite the increased rhetoric about and policy push to empower patients as consumers, insights from behavioral economics and psychology suggest patients may be poorly predisposed to perform this role and the decisions they have to make occur under very adverse conditions for quality decision making.²³

Yet we are now living in an exciting time of health care reform—a new era that, according to some optimistic accounts, will radically change health care decisions on many levels. The historic Patient Protection and Affordable Care Act (“Affordable Care Act” or “ACA”)²⁴ includes many reform initiatives aimed at improving health care decision-making. For example, the Affordable Care Act encourages the creation of ACOs that will share information and

20. See, e.g., Clark C. Havighurst & Barak D. Richman, *Who Pays? Who Benefits? Unfairness in American Health Care*, 25 NOTRE DAME J.L. ETHICS & PUB. POL’Y 493, 506–07 (2011).

21. See, e.g., Daniel Callahan, *The Fine Line Between Waste and Marginal Benefits*, HEALTH CARE COST MONITOR, <http://healthcarecostmonitor.thehastingscenter.org/daniel-callahan/the-fine-line-between-waste-and-marginal-benefits/> (last visited May 7, 2014).

22. See, e.g., Ana I. Balsa et al., *Clinical Uncertainty and Healthcare Disparities*, 29 AM. J.L. & MED. 203, 205 (2003) (observing the great degree of clinical discretion in medical practice and how “[n]either insurance contracts nor ethical and legal rules do a great deal to narrow the resulting clinical discretion.”); Clark C. Havighurst, *The Professional Paradigm of Medical Care: Obstacle to Decentralization*, 30 JURIMETRICS J. 415, 425 (1990) (“[P]ayers are essentially locked into underwriting all care meeting professional standards.”).

23. See generally Carl E. Schneider & Mark A. Hall, *The Patient Life: Can Consumers Direct Health Care?*, 35 AM. J.L. & MED. 7 (2009) (assessing the role of consumerism in health policy).

24. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

coordinate care among integrated networks of providers²⁵ and establishes insurance exchanges where patients can choose between health plans offering the same essential benefits, that are compared in standardized formats and that follow uniform enrollment procedures.²⁶ The Affordable Care Act also fosters the development of shared decision making between patients and providers²⁷ and develops a more comprehensive evidence base through more robust support of comparative effectiveness research.²⁸

A key consideration of this symposium is whether all these changes and many others occurring in the new era of health care reform (which includes, of course, more than just the Affordable Care Act) can meaningfully address the decision-making difficulties that continually hamper the health care system. Are law and policy helping in this regard or having negligible or even counterproductive impact? How are law and policy shaping the likely future direction of important health care decisions?

The topic is quite timely with the Affordable Care Act's implementation underway. But it is also vitally important because concern about and attention to decision making is a key piece of the ongoing debates over health care reform. With the Affordable Care Act's rollout, very divergent views are emerging about the nature and role of decision making in the health care system. For example, consider the new insurance exchanges. Putting aside the separate controversies surrounding the functionality of the HealthCare.gov website,²⁹ media reports and public commentary have yielded vastly different narratives about how patients will fare, even assuming the enrollment system has no technical snafus, in choosing health plans on the exchanges. According to a story in the *Washington Post*, navigators working to help formerly uninsured patients obtain coverage on the exchanges face a "daunting" and "herculean" task in assisting "vast numbers [of patients] who are confused by the myriad

25. See *id.* § 3022, 42 U.S.C. § 1395jjj (2012).

26. See *id.* § 1311, 42 U.S.C. § 18031.

27. See *id.* § 3506, 42 U.S.C. § 299b-36.

28. See *id.* § 6301, 42 U.S.C. § 1320e.

29. Healthcare.gov is the website for the Health Insurance Marketplace, the federally run insurance exchange available in states that have not elected to operate their own insurance exchanges. See Ctrs. for Medicare & Medicaid Servs., *Marketplace Overview*, HEALTHCARE.GOV, <https://www.healthcare.gov/health-insurance-marketplace/> (last visited May 7, 2014). Numerous technical problems with the website have hampered the enrollment process. See Robert Pear & Reed Abelson, *Insurers Claim Health Website is Still Flawed*, N.Y. TIMES (Dec. 1, 2013), <http://www.nytimes.com/2013/12/02/business/white-house-praises-gains-on-health-site.html>.

choices.”³⁰ This contrasts with an Associated Press (“AP”) story about multi-state employer Walgreen moving many of its employees to a private insurance exchange, modeled after the new government run exchanges. The AP report quoted Aon Hewitt executive Ken Sperling as saying that it was not a big deal for patients to choose a health plan: “It’s a bit more involved than buying a plane ticket, but I don’t think it’s more involved than buying a TV.”³¹ Clearly, views about the decisions on the insurance exchanges are so far apart that there is not even a common understanding about the decision-making process itself, what’s at stake, and the larger implications for health policy. Such confusion about, and sometimes inattention to, key decision-making issues in the health care system as it undergoes reform demonstrate the need for further scholarly examination.

* * *

Our symposium authors ably respond to this challenge, tackling the subject from interdisciplinary perspectives and in a nuanced way, eschewing pat explanations. They find considerable promise in some aspects of the Affordable Care Act and other reforms, yet they also identify key limitations and question whether decision making will become all the more complex and daunting in the new era of health care reform. They offer a comprehensive picture of the decision-making challenges that arise throughout the health care system. The articles are organized to address decision making at three different levels: (1) decisions by patients, (2) financial decisions regarding health care, and (3) the decisions made by government entities exercising a regulatory role.

Our first group of articles is designed around the theme of *Patient Decision Making: Birth, Death, and Daily Health*. The grouping reflects the idea that, for many of us, the prototypical health care decision occurs in the clinical context and involves medical treatment or at least some aspect of a patient’s overall health. Some of these decisions are the momentous, high-stakes choices often profiled in the popular press, such as the question of whether to withdraw medical interventions that are keeping a patient alive.³²

30. N.C. Aizenman, *For Insurance Exchanges, States Need ‘Navigators’—and Hiring Them is a Huge Task*, WASH. POST (Feb. 4, 2013), http://articles.washingtonpost.com/2013-02-04/national/36743424_1_insurance-exchanges-navigators-health-insurance.

31. Tom Murphy, *Walgreen Health Plans Go Private*, CHARLOTTE OBSERVER (Sept. 18, 2013), <http://www.charlotteobserver.com/2013/09/18/4324233/walgreen-health-plans-go-private.html#.UnrL27Eo670>.

32. See, e.g., *Cruzan v. Dir., Missouri Dep’t of Health*, 497 U.S. 261, 292 (1990) (holding that Missouri could require clear and convincing evidence of an incompetent patient’s wishes to withdraw life-sustaining treatment).

Other decisions are more incremental, such as whether to undergo a test designed to provide additional information that might, as a result, require a more difficult decision in the future—such as the choice of whether to undergo prenatal testing that may reveal information about the developing fetus.³³ And still other decisions appear to be so mundane, and are made so often, that we all but cease to recognize them as health care decisions at all—such as what to eat, whether to go to the gym, or whether to light up another cigarette.³⁴

Many of these clinical decisions take place in private, made by the patient and family members in consultation with doctors and other health care professionals. In these situations, the legal system has focused on ensuring that patients have both the information and the opportunities to make these treatment decisions and on creating procedures designed to minimize conflicts that might arise among decision makers.³⁵ Occasionally, however, these decisions play out on a very public stage, such as the disputes over end-of-life care for Karen Quinlan, Nancy Cruzan, and, most recently, Terri Schiavo.³⁶ In other situations the public stage is a political one, with legislators seeking to mandate the provision of specific information before patients can elect certain medical treatments (such as new laws requiring pregnant women to receive mandatory ultrasounds prior to consenting to abortion).³⁷ Regardless of personal views on the merits of these disputes, it is clear that these intimate health care decisions may be altered irrevocably when they are forced to take place in a public context. Moreover, it is far from certain that simply presenting patients (and doctors) with more information—whether from the scientific literature, the hospital legal department, or the legislature—

33. See, e.g., Am. College of Obstetricians and Gynecologists Comm. on Genetics & Soc'y for Maternal-Fetal Med., *The Use of Chromosomal Microarray Analysis in Prenatal Diagnosis*, COMMITTEE OPINION, No. 581, 1 (Dec. 2013), <http://www.acog.org/~media/Committee%20Opinions/Committee%20on%20Genetics/co581.pdf?dmc=1&ts=20140126T1021504634> (offering “recommendations regarding the application of chromosomal microarray technology in the prenatal setting”).

34. Cf. 42 U.S.C. § 300gg-17(b) (2012) (describing the potential scope of wellness and prevention programs).

35. See, e.g., Right to Natural Death; Brain Death, N.C. GEN. STAT. §§ 90-329 to -324 (2013).

36. See Sandra H. Johnson, *Quinlan and Cruzan: Beyond the Symbols*, in *HEALTH LAW AND BIOETHICS: CASES IN CONTEXT* 53, 53 (Sandra H. Johnson et al. eds., 2009).

37. See, e.g., Woman's Right to Know Act, N.C. GEN. STAT. § 90-21.85 (2013) (mandating that pregnant women undergo a physician-administered ultrasound before obtaining an abortion), *invalidated by* *Stuart v. Loomis*, 2014 U.S. Dist. LEXIS 6194 (M.D.N.C. Jan. 17, 2014).

automatically leads to better decisions.³⁸ In short, bombarding people with information about their health care choices, from ever-changing dietary or screening recommendations to detailed advanced directive forms, may just as easily lead to paralysis as to perspicacity.

To the extent the law seeks to improve these types of decision making, the papers in this first group must consider whether the law is responsive to the concrete difficulties faced by patients and their caregivers. Professor Lois Shepherd from the University of Virginia explores some of these issues in *The End of End of Life Law*.³⁹ Noting that the legal system has, over time, developed complex rules that treat end-of-life decisions differently than other important medical decisions, Professor Shepherd argues that end-of-life decisions instead “should be approached like other important questions about medical care—with consideration to patients’ wishes, values, interests, and relationships, and without special laws, special burdens of proof, or unique requirements for documentation.”⁴⁰ Shifting the focus to more common health care choices, Dr. David Orentlicher of the Indiana University Robert H. McKinney School of Law highlights problems in our approach to daily wellness decisions in *Health Care Reform and Efforts to Encourage Healthy Choices by Individuals*.⁴¹ Dr. Orentlicher is particularly critical of the Affordable Care Act’s attempts to improve individual wellness decisions through menu labeling requirements and employer wellness programs. He argues that the lack of empirical evidence as to which strategies work may have the unintended effect of discouraging healthy choices and undermining the goal of improving access to health care.⁴² These articles illustrate the dangers inherent in developing static rules that are designed to improve patient decision making, however well-intentioned those rules may be.⁴³

38. See, e.g., Harlan M. Krumholz, *Informed Consent to Promote Patient-Centered Care*, 303 JAMA 1190, 1190 (2010) (concluding with regard to the legal requirements of informed consent that “current efforts to inform patients are inadequate,” the information distributed “ha[s] limited educational value,” and many patients do not read the disclosure forms and “misunderstand the benefits and risks” of their treatments).

39. See generally Lois Shepherd, *The End of End of Life Law*, 92 N.C. L. REV. 1693 (2014) (discussing the rules and changes in end of life law).

40. *Id.* at 1696.

41. See David Orentlicher, *Health Care Reform and Efforts to Encourage Healthy Choices by Individuals*, 92 N.C. L. REV. 1637, 1657 (2014).

42. *Id.* at 1639–42.

43. The live symposium also featured a talk on reproductive decision making. Dr. Anne Drapkin Lyerly, Assoc. Dir. of the Ctr. for Bioethics & Assoc. Professor of Soc. Med., Univ. of N.C. Sch. of Med., Address at the University of North Carolina Law

Our second group of articles, designed around the theme of *Financial Decision Making: Cost and Coverage*, recognizes the core financial component of many health care decisions. For patients, financial considerations inform not only the choice of insurance, but in many cases the choice of treatment. While the Affordable Care Act sought to make it easier for individuals to compare health insurance policies on the insurance exchanges by mandating a standardized summary of benefits and costs,⁴⁴ there is no guarantee that patients will be able to use that information to make wise choices. Financial decisions loom large for insurers as well, who must decide whether to participate on a state insurance exchange and, if so, which plans to offer.⁴⁵ State governments also must make a range of decisions with implications for health care costs and insurance coverage, most notably whether or not to expand the existing Medicaid program, but also decisions regarding whether to operate a state-based insurance exchange and how to choose a benchmark health plan for the state.⁴⁶

The papers in this group address the financial implications of health care decisions for both consumers and state governments. In *Can Patients in the U.S. Become Savvy Health Care Consumers?*, Dr. Peter Ubel of Duke University questions whether efforts to shift health care costs to patients have improved patients' health care decisions.⁴⁷ While acknowledging that forcing patients to have "skin in the game" ultimately may decrease health care expenditures,⁴⁸ Dr. Ubel identifies key clinical barriers that nevertheless prevent patients from becoming the types of educated consumers they are in other

Review Symposium: Information and Autonomy in Reproductive Decisionmaking (Oct. 4, 2013).

44. See Patient Protection and Affordable Care Act, sec. 2715, 42 U.S.C. § 300gg-15 (2012) ("Development and utilization of uniform explanations of coverage documents and standardized definitions").

45. See, e.g., Reed Abelson, *Choice of Health Plans to Vary Sharply from State to State*, N.Y. TIMES (June 16, 2013), http://www.nytimes.com/2013/06/17/health/choice-of-health-plans-to-vary-sharply-from-state-to-state.html?_r=0 (describing range of insurers and products available in different states).

46. See, e.g., Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2607 (2012) (holding that Medicaid expansion must be voluntary); Ctrs. for Medicare & Medicaid Servs., *North Carolina EHB Benchmark Plan*, CENTERS FOR MEDICARE & MEDICAID SERVICES, <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/north-carolina-ehb-benchmark-plan.pdf> (last visited May 7, 2014); Ctrs. for Medicare & Medicaid Servs., *What is the Marketplace in My State?*, HEALTHCARE.GOV, <https://www.healthcare.gov/what-is-the-marketplace-in-my-state/> (last visited May 7, 2014) (identifying whether there is a state exchange or whether residents should use the federal marketplace).

47. See Peter Ubel, *Can Patients in the U.S. Become Savvy Health Care Consumers?*, 92 N.C. L. REV. 1749, 1750 (2014).

48. *Id.*

settings, including: a lack of price information; too little time to consider the available information when making urgent health care decisions; the difficulty of fitting discussions about the cost of care into the traditional model of the doctor-patient relationship; and the mismatch between financial incentives and clinical benefits for many health care services.⁴⁹ Unless these problems are addressed, Dr. Ubel argues that patients will face higher costs without a concomitant improvement in their ability to make decisions about their medical treatments.⁵⁰ Professor Allison Hoffman of the University of California Los Angeles School of Law expands on the theme of patients' financial decisions in *Insurance and Financial Security After the Affordable Care Act*.⁵¹ Professor Hoffman focuses on the degree to which the protections enacted by the Affordable Care Act will reduce "financial insecurity" due to health care costs for different groups of patients.⁵² While acknowledging that the law will, to some extent, reduce financial insecurity for each group, Professor Hoffman concludes that even after health care reform, patients will face significant variations in their exposure to health care expenses.⁵³

Professor Mark Hall of Wake Forest University shifts the focus to state financial decision making in *States' Decisions Not to Expand Medicaid*.⁵⁴ Professor Hall focuses on two of the major decisions required of states under the Affordable Care Act: (1) whether to create a state-based insurance exchange, a decision he argues has been made on counterintuitive political grounds; and (2) whether to expand Medicaid, a decision he argues should be based on financial considerations that weigh heavily in favor of expansion.⁵⁵ Examining and rejecting the common rationales for not expanding Medicaid—chiefly, concerns for patient dependency and the expense of the program—Professor Hall argues that the states that have refused expansion appear to be acting instead out of political expediency or ideology.⁵⁶ In Professor Hall's view, such "spiteful refusal of federal

49. See generally *id.* (arguing about the costs, benefits, and challenges surrounding increased patient involvement).

50. *Id.* at 1784–85.

51. See generally Allison K. Hoffman, *Insurance and Financial Security After the Affordable Care Act*, 92 N.C. L. REV. 1482 (2014) (discussing how the Affordable Care Act conceives of financial security and its varied impacts on different groups).

52. *Id.* at 1484.

53. See *id.* at 1533.

54. See generally Mark A. Hall, *States' Decisions Not to Expand Medicaid*, 92 N.C. L. REV. 1459 (2014) (discussing some states' opposition to expanding Medicaid and the rationales provided in support for these choices).

55. *Id.* at 1459–63.

56. *Id.* at 1477.

funds in order to undermine the ACA is at least callous, if not reprehensible.”⁵⁷ In short, it is clear that health care reform has not resolved—and indeed may have exacerbated—many of the structural and political barriers to rational financial health care decision making.

The third and final grouping of articles, *Regulatory Decision Making: The Government’s Role in Information and Quality Control*, considers larger governmental oversight and regulatory design decisions in the health care system. While the role of major legislative decisions that shape the health care system—such as the passage of the Affordable Care Act itself⁵⁸—may be apparent to most observers, the government’s extensive role in operational decisions affects the provision of health care on an ongoing, if more mundane, basis. From the organization of the governmental agencies charged with implementing the Affordable Care Act to standards for the collection and analysis of data, regulatory decisions have implications for virtually every aspect of health care.⁵⁹

The papers in this group address this governmental role, particularly as it relates to information and quality control. Dr. Aaron Kesselheim of Harvard Medical School and Professor Michelle Mello of the Harvard School of Public Health address one aspect of this problem—government regulation of the promotion of pharmaceutical products—in *Prospects for Regulation of Off-Label Drug Promotion in an Era of Expanding Commercial Speech Protection*.⁶⁰ The authors focus on the implications of a recent First Amendment case in the Second Circuit, *United States v. Caronia*,⁶¹ for the ability of the Food and Drug Administration to restrict a manufacturer’s promotion of products “off-label,” beyond the uses for which the drugs are approved.⁶² Arguing that “years of experience with industry marketing practices leading to dangerous, non-evidence-based off-label uses of medical products justify the need for regulation in this

57. See *id.* at 1476–77.

58. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

59. See, e.g., 42 U.S.C. §§ 1320d–1320d-9 (2012) (requiring standards for the electronic transmission of health information); *The Center for Consumer Information & Insurance Oversight: Ensuring the Affordable Care Act Serves the American People*, CENTERS FOR MEDICARE & MEDICAID SERVICES, <http://cms.gov/ccio/index.html> (last visited May 7, 2014) (implementing provisions of Affordable Care Act).

60. See generally Aaron Kesselheim & Michelle M. Mello, *Prospects for Regulation of Off-Label Drug Promotion in an Era of Expanding Commercial Speech Protection*, 92 N.C. L. Rev. 1539 (2014) (addressing the intersection of the First Amendment and FDA regulation of pharmaceuticals).

61. 703 F.3d 149 (2d Cir. 2012).

62. Kesselheim & Mello, *supra* note 60, at 1543.

arena,”⁶³ Kesselheim and Mello seek to identify strategies that would permit the government to restrict dangerous behavior without running afoul of First Amendment rights to free speech.⁶⁴

Professor Kristen Madison, Professor of Law and Health Sciences at Northeastern University, addresses the federal government’s growing role with regard to the collection and use of health care data in her essay, *Health Regulators as Data Stewards*.⁶⁵ Rather than serving merely as a repository for such data, Professor Madison argues that the federal government in essence functions as a “data steward,” managing this information and thereby influencing the type of information that is available to health care decision makers.⁶⁶ Professor Madison argues that the government must work to ensure that this data is better used to improve regulatory decision making, particularly by creating “an evidence base for regulatory and programmatic interventions.”⁶⁷

Finally, in *Private Certifiers and Deputies in American Health Care*, Professor Frank Pasquale of the University of Maryland Francis King Carey School of Law turns to the government’s role in setting standards for a variety of health care items and services, with a particular focus on the recent practice of outsourcing such decisions to private organizations.⁶⁸ Professor Pasquale examines two outsourcing models: private certification, in which private firms certify that a technology or service meets applicable standards, and deputization, in which private firms are charged with disciplining health care providers who fail to meet those standards.⁶⁹ While noting that these approaches may offer a more flexible form of administrative governance in complex and rapidly changing fields such as health care, Professor Pasquale also identifies the very real potential for abuse of public programs by private entities.⁷⁰ Professor Pasquale ends by urging a more “seamless integration of clinical

63. *Id.* at 1599.

64. *Id.* at 1599–60.

65. See generally Kristin Madison, *Health Regulators as Data Stewards*, 92 N.C. L. REV. 1605 (2014) (addressing the intersection of big data, federal regulation, and health care).

66. *Id.* at 1607–08.

67. *Id.* at 1609.

68. See generally Frank A. Pasquale, *Private Certifiers and Deputies in American Health Care*, 92 N.C. L. REV. 1661 (2014) (addressing the interaction between government’s regulatory role in setting standards and the on-going outsourcing phenomenon).

69. *Id.* at 1662.

70. *Id.* at 1662–63.

decision support, revenue cycle management, and fraud detection”⁷¹ if public-private partnerships are to serve their intended purpose. Overall, these papers ably illustrate the complexity of regulatory decision making in a post-health care reform world.

* * *

The perils of decision making, and the promise of improvement, have been well documented by researchers such as Dan Ariely:

[W]e are not only irrational, but *predictably irrational*—[] our irrationality happens the same way, again and again. Whether we are acting as consumers, businesspeople, or policy makers, understanding how we are predictably irrational provides a starting point for improving our decision making and changing the way we live for the better.⁷²

These perils are only magnified when the decisions at issue concern health care, where faulty choices may affect the health and well-being (not to mention the livelihood) of myriad patients and health care providers. Decisions pervade every aspect of health care—from the mundane to the momentous, from the clinic to the courtroom, for everyone from patients to policymakers. The participants in this symposium seek to illuminate the pressures on, and the potential for, productive decisions as the health care system undergoes transition. In our view, they admirably succeed in advancing the academic conversation and larger understanding about the key role of decision making in the new era of health care reform.

71. *Id.* at 1690.

72. DAN ARIELY, *PREDICTABLY IRRATIONAL: THE HIDDEN FORCES THAT SHAPE OUR DECISIONS* xx (1st ed. 2008).